K042841 1/2

DEC 21 2004

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: M²a™/C²a™ Acetabular System

Common Name: Metallic Acetabular System

Classification Name:

1. Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis (21 CFR 888.3330)
2. Hip joint metal/metal semi-constrained, with a cemented acetabular component prosthesis (21 CFR 888.3320)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Biomet devices:

K993438 - Metal on Metal Acetabular System
K003363 - M²a™ 32mm Taper System
K861114 - Mallory/Head PF Acetabular Component

Device Description: The M²a™/C²a™ Acetabular System consists of a titanium outer acetabular shell with a cobalt alloy metallic liner for metal on metal articulation.

The acetabular shells are hemispherical in shape to closely match the natural acetabulum. Two screw holes in the dome allow for additional fixation by the use of screws. The outer surface of the shells are covered with Biomet's plasma sprayed coating.

The metallic cobalt alloy bearing liner fits into the outer shell by means of a taper similar to the taper used for the attachment of a modular head to a femoral stem. The metallic liners articulate with cobalt alloy modular heads.

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56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639

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574.267.8137

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biomet@biomet.com

Intended Use: The M²a™/C²a™ Acetabular System is intended for cemented or non-cemented use in cases of:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Revision procedures where other treatment or devices have been unsuccessful
5) Treatment of non-union, femoral neck fracture, trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques

Summary of Technologies: The technological characteristics of the new device are similar of identical to the predicates.

Non-Clinical Testing: None provided

Clinical Testing: None provided.

All trademarks are property of Biomet, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2004

Ms. Patricia S. Andborn Beres
Senior Regulatory Specialist
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46582

Re: K042841
Trade/Device Name: M^2a / C^2a™ Acetabular System
Regulation Number: 888.3330; 888.3320
Regulation Name: Hip joint metal/semi constrained, with uncemented acetabular component prosthesis; Hip joint metal / metal semi-constrained acetabular component prosthesis
Regulatory Class: III
Product Code: KWA, JDL
Dated: November 26, 2004
Received: November 29, 2004

Dear Ms. Andborn Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042841

Device Name: M^2a™/C^2a™ Acetabular System

Indications For Use:

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5) Treatment of non-union, femoral neck fracture, trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Page 1 of 1

510(k) Number K042841